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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,078	10/21/2003	Jaymin C. Shah	PC23164A	4825

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,078	SHAH, JAYMIN C.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-4,6-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

Summary

Receipt of Applicants Remarks and Amended claims filed on July 2, 2007 is acknowledged. Claims 1, 3-4 and 6-18 remain pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (WO 97/41896).

Johnson discloses ziprasidone complexed with a cyclodextrin. Preferred cyclodextrins are SBECD and HPBCD. The salt/cyclodextrin inclusion complex preferably provides an amount of ziprasidone of at least 2.5mgA/mL when the complex is dissolved in water at 40% w/v. A variety of ziprasidone salts are preferred, including mesylate, esylate, besylate, tartate, napsylate and tosylate (abstract). The complex can be administered as an injectable (page 4, lines 18-20).

Regarding claim 4, Johnson discloses the cyclodextrin can be in a wide range of concentrations from about 5 wt % (w/v) to over 100 wt% (w/v). It is also disclosed that at higher the percentage of cyclodextrins, the formulations become what viscous (page 9, line 24 through page 10, line 2). Therefore, the cyclodextrin reads on applicant's viscosity agent. Crystalline inhibitors, polar solvents used in the composition include tetrahydrofuran, water, lower alcohol (page 10, lines 10-18).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues all components of the formulation are not disclosed together. The examiner disagrees. The claims recite a formulation comprising ziprasidone and a viscosity agent. Johnson discloses cyclodextrin increases the viscosity as its concentration is increased in the formulation (page 10, lines 1-2). Therefore, the complex of Johnson meets the limitations of the instant claims.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 6-7, it is unclear what viscosity agents are being claimed. It is suggested Applicant use the claim language "said viscosity agent is selected from the group consisiting of..." in order to be in proper Markush from. Furthermore, it is unclear what copolymers and terpolymers of the foregoing include or combinations thereof.

Regarding Claim 8, It is unclear what the viscosity agent is limited to be. The claim recites the viscosity agent is a cellulose derivative, however, polylactides and polyglycolides are also included. The examiner has interpreted the claims to further limit possible cellulose derivatives, but to also allow for polylactides and polyglycolides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathi et al. (US patent 6,117,949).

Rathi discloses a water soluble biodegradable ABA- or BAB-type triblock polymer that is made up of a major amount of a hydrophobic polymer made of a poly(lactide-co-glycolide) copolymer or poly(lactide) polymer as the A-blocks and a minor amount of a hydrophilic polyethylene glycol polymer B-block, having an overall weight average molecular weight of between about 2000 and 4990, and that possesses reverse thermal gelation properties. The composition is administered to a warm-blooded animal as a liquid by parentarel, ocular, topical, inhalation, transdermal, vaginal, transurethral, rectal, nasal, oral, pulmonary or aural delivery means and is a gel at body temperature. The composition may also be administered as a gel. The drug is released at a controlled rate from the gel which biodegrades into non-toxic products. The release rate of the drug may be adjusted by changing various parameters such as hydrophobic/hydrophilic component content, polymer concentration, molecular weight and polydispersity of the triblock polymer. Because the triblock polymer is amphiphilic, it functions to increase the solubility and/or stability of drugs in the composition. (Abstract). The term "gel" includes both the semisolid gel state and the high viscosity state that exists above the gelation temperature. When cooled below the gelation temperature, the gel spontaneously reverses to reform the lower viscosity solution (column 6, lines 23-38). The water soluble polymer reads on Applicants instantly claimed viscosity agent. Anti-psychotics including ziprasidone are disclosed (column 13, lines 48-64). Since Rathi discloses the polymer is useful in solublizing the drug, absent a showing to the contrary, it is the position of the examiner that the ziprasidone is solubilized in the composition of Rathi.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rathi et al. (US patent 6,117,949).

The teachings of Rathi are discussed above and applied in the same manner.

Rathi does not disclose the viscosity of the formulation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have adjusted the viscosity of the gel in order to meet the desired consistency and benefits. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). Since the reference discloses the same formulation for the same function, it would have been obvious to optimize the viscosity in order to obtain optimal therapeutic/functioning properties.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 97/41896).

The teachings of Johnson are discussed above and applied in the same manner.

Rathi does not disclose the viscosity of the formulation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have adjusted the viscosity of the gel in order to meet the desired consistency and benefits. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). Since the reference discloses the same formulation for the same function, it would have been obvious to optimize the viscosity in order to obtain optimal therapeutic/functioning properties.

Claims 1, 3-4, 6-10, 12, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathi et al. (US patent 6,117,949) in view of Johnson et al. (WO 97/41896).

The teachings of Rathi are discussed above and applied in the same manner.

Rathi does not disclose the ziprasidone complexed with a cyclodextrin.

The teachings of Johnson are discussed above and applied in the same manner.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the cyclodextrin/ziprasidone complex into the composition of Rathi since Johnson discloses that the solubility of the compounds form stable inclusion complexes with cyclodextrins and that such inclusion complexes are

highly water soluble relative to the non-complexed drug. Furthermore, formulations of pharmaceutical dosage forms is frequently hampered by poor agueous solubility and/or stability of the drug of interest, which in turn can severly limit its therapeutic application. Increasing drug solubility and stability through appropriate formulation can lead to increased therapeutic efficacy for the drug (Johnson, page 1, lines 6-10).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 97/41896) in view of Reel et al. (US Patent 4,512,986).

The teachings of Johnson are discussed above and applied in the same manner.

Johnson does not disclose the use of pyrrolidone as a co-solvent.

Reel discloses compositions suitable for parenteral administration. The compositions comprise suspending agents including sodium carboxymethylcellulose and polyvinyl pyrrolidone (column 7, lines 10-23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the adjuncts of Reel with the composition of Johnson since Johnson discloses the use of suspending agents/viscosity adjusting agents. It would be within the knowledge of the skilled artisan to use any suitable agent to perform its intended function of suspending or adjusting the viscosity of a composition for parenteral administration.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 97/41896) in view of Bornstein (US Patent 4,029,782).

The teachings of Johnson are discussed above and applied in the same manner.

Johnson does not disclose the use of a cellulose viscosity agent.

Bornstein discloses a suspension for parenteral administration comprising water, a pharmaceutically acceptable surfactant, lecithin, and viscosity adjusting agents (abstract). Sodium carboxymethylcellulose is disclosed as a viscosity adjusting agent in an amount of 0.1-2.0% (w/v) (column 4, lines 40-44). The surfactant may be present in the amount of 0.1-1.0% (w/v) (column 4, lines 55-56).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the adjuncts of Bornstein with the composition of Johnson in order to obtain an inject able composition which allows for the prolongation of therapeutic blood levels. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various sanitizing compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426(CCPA 1971).

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615